REMARKS

Rejection of Claims under 35 U.S.C. § 103(a)

The Office Action of February 26, 2008 has been carefully reviewed. Applicant appreciates the attention that the Examiner has given to this application. By virtue of the amendments and arguments presented in this response, we believe the application to be condition for allowance. Reconsideration is courteously requested.

Claims 14-19, 22-24 and 26-31 are currently pending. Claims 1-13 and 25 have been cancelled without prejudice. Claims 14, 15, 19, 22-24 and 26-31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,676,659 issued to Hutchins et al. ("Hutchins et al.") in view of U.S. Publication No. 2003/0078473 by Richardson ("Richardson") further in view of U.S. Patent No. 6,740,277 issued to Howell et al. ("Howell et al."). Claims 17 and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hutchins et al. in view of Richardson and Howell et al. and further in view of U.S. Patent No. 6,017,339 issued to Sadamasa ("Sadamasa").

Applicant respectfully submits that neither Hutchins et al., Richardson, Howell et al., nor Sadamasa, either alone or in combination, teach or suggest a multi-lumen catheter comprising at least the following elements of Applicant's independent claims 14 and 26:

Claim 14:

- at least one lumen "sized to receive a 0.035 inch guidewire;"
- a distal tip having a tapered portion of "approximately 3 millimeters or less;" and
- a distal terminus having an outer diameter "measuring less than approximately 0.063 inch"

Claim 26:

- at least one lumen "sized to receive a 0.035 inch guidewire;"
- a distal tip having a tapered portion with "a length within the range of 1.5 mm to 4.5 mm;" and

- a distal terminus having "an outer diameter within the range of 0.055 inch to 0.063 inch."

The Office Action acknowledges that Hutchins et al. fails to disclose Applicant's claimed taper length or Applicant's claimed outer diameter for the distal terminus. Applicant respectfully submits that Richardson fails to remedy the deficiencies of Hutchins et al. Richardson discloses a biliary guide catheter 30 having a single lumen 31 into which a pulling biliary catheter 40 can be inserted. See Richardson at Paragraphs [0040] and [0041]. Richardson discloses a tapered tip and a broad range for the taper length, stating that "[t]he distal taper generally begins approximately 0.10 to 5.0 centimeters from the distal most tip." See Richardson at Paragraph [0038]. However, Richardson does not recognize the desirability of, or teach one of skill how to design, a multi-lumen catheter having Applicant's 0.035 guidewire-compatible distal tip with Applicant's selected, shorter taper length and low profile distal terminus outer diameter. Indeed, Richardson teaches away from Applicant's invention, stating that "a shorter and steeper tapering requires less advancement, yet makes dilation more immediate, and possibly more difficult." See Richardson at Paragraph [0039]. Accordingly, the combination of Hutchins et al. and Richardson does not disclose, teach or suggest the invention of Applicant's independent claims 14 and 26.

Applicant respectfully submits that Howell et al. fails to remedy the deficiencies of Hutchins et al. and Richardson. Howell et al. discloses an over-the-needle catheter comprised of a tube with a single lumen extending through the tube. See Howell at Abstract. Howell et al. merely discloses that the tubular body can have an outer diameter in a range of 0.020 to 0.140 inches but fails to teach or suggest a multi-lumen catheter having a 0.035 guidewire-compatible distal tip with Applicant's claimed taper length and distal terminus outer diameter.

Howell et al. incorporates by reference U.S. Patent No. 4,588,398 issue to Daugherty et al. ("Daugherty et al."). Applicant respectfully submits that Daugherty et al. also fails to remedy the deficiencies of Hutchins et al. and Richardson. Daugherty et al. discloses a single-lumen over-the-needle catheter having a range of taper lengths and diameters. However, Daugherty et al. fails to teach or suggest a multi-lumen catheter having a 0.035 guidewire-compatible distal tip with Applicant's claimed taper length and distal terminus outer diameter.

Both Howell et al. and Daugherty et al. disclose an over-the-needle, single-lumen catheter and fail to disclose a multi-lumen catheter. Similarly, Richardson also fails to disclose a multi-lumen catheter. Applicant respectfully submits that Howell et al., Daugherty et al., and Richardson cannot be combined with Hutchins et al. to arrive at Applicant's invention, as doing so fails to appreciate the technological difficulty confronted by one skilled in the art to design a multiple lumen catheter having Applicant's claimed taper length and distal terminus outer diameter.

Applicant's claimed taper length and distal terminus outer diameter provide for a multi-lumen catheter having a low profile and short tapered tip. The benefit of a small profile is that it "facilitates penetration through small openings and expands them gradually as the wider more proximal areas of the catheter shaft proceed through." See Paragraph [0003] of the '496 Application as published. The benefit of multiple lumens is that "[p]roviding multiple lumens in the catheter shaft is one way to enhance the utility of the catheter as a conduit for other devices and treatments." See Paragraph [0006] of the '496 Application as published. The technological difficulty, however, lies in that "attempts to address all the above design considerations [multiple lumens and a small profile] in one catheter leads to compromises of each design objective. Provision of multiple large lumens compromises the ability to provide a low profile distal tip. Though tapering the tip to a reduced profile is one way to address that compromise, tapering the tip to a very low profile over a short distance to provide a short tip length is difficult because wall thickness necessarily becomes reduced to the point where lumens and components within them can be exposed to other lumens or to the exterior of the shaft." See Paragraph [0007] of the '496 Application as published.

Applicant disagrees with the Office's assertion that "it would have been obvious to one of ordinary skill in the art to use the desired of increase the probability of initially getting into a smaller opening such as the orifice of Vater as suggested by Richardson and teaching of how to make a tapered tip catheter as suggested Howell to modify the tip of Hutchins catheter so that it too would have the same advantage. With respect to the dimensions that claimed by the applicant, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art." Final Office Action, page 5.

Applicant respectfully submits that due to the limitations imposed by routine design and manufacturing techniques, it would not have been obvious to one skilled in the art to combine the teachings of Richardson and Howell et al. with Hutchins to arrive at the multi-lumen catheter claimed by Applicant. As set forth in the November 30, 2007 Declaration under 37 C.F.R. § 1.132 of Harold M. Aznoian (¶ 8), the features of the claimed invention were not attainable with routine skill. For example, known manufacturing techniques did not provide the ability to prevent heating of unintended areas of the shaft; and without this degree of control it was impossible to keep the tip short while achieving a lower profile outside diameter over a short taper length. See id. at ¶ 8(a). Known techniques also did not provide for a proximal and distal clamp design in connection with mandrels during the necking process to correctly form the distal profile. See id. at ¶ 8(b). Also, conventional manufacturing methods did not provide for adequate heating, cooling and pulling processes. See id. at ¶ 8(c). For at least these reasons, Applicant respectfully submits that one of ordinary skill in the art applying known techniques would not have been able to create a multi-lumen catheter having a 0.035 guidewire-compatible distal tip, Applicant's claimed taper length, and distal terminus outer diameter.

Claims 15, 17-19 and 22-24 depend, directly or indirectly, from claim 14. For the same reasons as stated above for claim 14, Applicant respectfully submits that claims 15, 17-19 and 22-24 are in condition for allowance. Claims 27-31 depend, directly or indirectly, from claim 26. For the same reasons as stated above for claim 26, Applicant respectfully submits that claims 27-31 are also in condition for allowance.

Although we have responded to each of the Examiner's grounds for rejection, we are particular concerned at this point that the Examiner has found it necessary to cite a wide variety of references, drawing specific details and features from the various references and combining these bits of information in an attempt to reach the claimed invention. The selection and combination of such isolated details and features could have been suggested only by the instant specification. With all due respect, we believe that the Examiner's approach amounts to an improper, hindsight reconstruction of the claimed invention.

CONCLUSION

Applicant's discussion of particular positions of the Examiner does not constitute a concession with respect to any positions that are not expressly contested by the Applicant. Applicant's emphasis of particular reasons why the claims are patentable does not imply that there are not other sufficient reasons why the claims are patentable, nor does it imply the claims were not allowable in their original form.

Applicant respectfully submits that all pending claims are in condition for allowance and requests withdrawal of the current rejections. If the Examiner believes that an interview would expedite prosecution of the present application, the Examiner is encouraged to contact Applicant's Attorney at the number below.

Dated: April 28, 2008

Respectfully submitted,

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